

containing 3 mg of drospirenone in 900 ml of water at 37°C ( $\pm$  5 °C) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm, including 6 covered glass vessels and 6 paddles,

about 0.01 mg to about 0.05 mg of 17 $\alpha$ -ethinylestradiol, and

one or more pharmaceutically acceptable carriers,

the composition being in an orally administrable form.

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Cont 46. A pharmaceutical kit comprising a number of separately packaged, individually removable, and orally administrable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units each comprise a combination of:

drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone has a surface area of more than 10 000 cm<sup>3</sup>/g, and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg.

47. A pharmaceutical kit comprising a number of separately packaged, individually removable, and orally administrable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units each comprise a combination of:

drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone is in a form having a dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C ( $\pm$  5 °C) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm, including 6 covered glass vessels and 6 paddles, and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg.

48. A pharmaceutical kit comprising a number of separately packaged, individually removable, and orally administrable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 28 consecutive days,

wherein at least 21 of said daily dosage units comprise a combination of:

micronized drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone has a surface area of more than 10 000 cm<sup>3</sup>/g, and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg, and wherein at least 1 but no more than 7 of said daily dosage units contain 17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg and contain no drospirenone.

49. A pharmaceutical kit comprising a number of separately packaged, individually removable, and orally administrable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 28 consecutive days, wherein at least 21 of said daily dosage units comprise a combination of:

micronized drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone has a dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C ( $\pm$  5 °C) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm, including 6 covered glass vessels and 6 paddles, and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg, and wherein at least 1 but no more than 7 of said daily dosage units contain 17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg and contain no drospirenone.

50. A composition of claim 45, 47 or 49, wherein at least 80% of said drospirenone is dissolved within 20 minutes by the stated test.

51. A composition or kit according to claim 44, 45, 46, 47, 48 or 49, wherein the 17 $\alpha$ -ethinylestradiol is in micronized form.

52. A composition or kit according to claim 44, 45, 46, 47 or 48, wherein the drospirenone is sprayed from a solution onto particles of an inert carrier.

✓ 53. A composition or kit according to claim 44, 45, 46, 47, 48 or 49, wherein the amount of drospirenone is from 2.5 to 3.5 mg.

✓ 54. A composition or kit according to claim 44, 45, 46, 47, 48 or 49, wherein the amount of 17 $\alpha$ -ethinylestradiol is from 0.015 to 0.04 mg.

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✓ 55. A composition or kit according to claim 44, 45, 46, 47, 48 or 49 comprising a carrier effective to promote dissolution of drospirenone and ethinylestradiol.

✓ 56. A composition or kit according to claim 55 wherein said carrier is polyvinylpyrrolidone.

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